UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

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TAMARA CARTER and DAVID CARTER, Plaintiffs, v. JOHNSON & JOHNSON; ETHICON, INC.; and ETHICON LLC, Defendants.	Case No. 2:20-cv-01232-KJD-VCF ORDER

Presently before the Court is Defendant's Motion to Limit Opinions of Bruce Rosenzweig, M.D. (#199). Plaintiffs filed a response in opposition (#208) to which Defendant replied (#218).

I. Factual and Procedural Background

This is a products liability action involving two prescription medical devices– Prolift and TVT. On July 23, 2010, at St. Rose Dominican Hospital in Las Vegas, Nevada, Dr. Gregory Hsieh implanted a Prolift device for Plaintiff Tamara Carter's ("Mrs. Carter") posterior pelvic prolapse ("POP") and a TVT mid-urethral sling for Mrs. Carter's stress urinary incontinence ("SUI"). Mrs. Carter alleges that these medical devices caused her injuries, and that Defendants are liable under claims of strict liability for failure to warn and for design defect. Her husband, Plaintiff David Carter ("Mr. Carter") raises a loss of consortium claim. Additionally, Plaintiffs claim that Defendants' conduct was malicious, oppressive, willful, wanton, reckless, and grossly negligent. Defendants ("Ethicon") deny Plaintiffs' allegations and assert that Prolift and TVT were state of the art at the time of implant, that Mrs. Carter's alleged injuries pre-dated her surgery, that Mrs. Carter assumed the risks, and that Mrs. Carter's own actions contributed to her injuries.

Dr. Bruce Rosenzweig is a urogynecologist and professor of obstetrics and gynecology. Defendant Ethicon seeks to limit Rosenzweig's testimony by requesting that the Court preclude him from testifying about Prolift, because he only issued an expert report

involving TVT. Generally, Plaintiffs do not oppose that limitation. Therefore, the Court limits Dr. Rosenzweig's testimony by only allowing him to testify regarding TVT.

Next, Defendant seeks to have the Court prevent Rosenzweig from testifying that non-synthetic mesh procedures are safer alternatives to synthetic mesh. Further, Defendant seeks to preclude Rosenzweig from criticizing the mechanically-cut mesh, as opposed to laser cut mesh.

I. Analysis

A. Legal Standard

Federal Rule of Evidence ("Rule") 702 permits a "witness who is qualified as an expert by knowledge, skill, experience, training, or education [to] testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." The Supreme Court gave expanded direction on Rule 702 in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). In Daubert, the Court held that Rule 702 imposed "a special obligation upon a trial judge to 'ensure that any and all scientific testimony… is not only relevant, but reliable.'" See Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1999). The Court expanded this gatekeeping obligation to all expert testimony. Id. at 147. Daubert "established that, faced with a proffer of expert scientific testimony, the trial judge, in making the initial determination whether to admit the evidence, must determine whether the expert's testimony reflects (1) "scientific knowledge," and (2) will assist the trier of fact to understand or determine a material fact at issue." Daubert, 509 U.S. at 592. The "focus must be solely on principles and methodology, not on the conclusions that they generate." Id. at 595.

The Ninth Circuit has emphasized that "Rule 702 is applied consistent with the liberal thrust of the Federal Rules and their general approach of relaxing the traditional barrier to opinion testimony." Jinro Am. Inc. v. Secure Investments, Inc., 266 F.3d 993, 1004 (9th Cir. 2001). "An expert witness–unlike other witnesses–is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation, so long as the expert's opinion

[has] a reliable basis in the knowledge and experience of his discipline." Id. (citations and quotation marks omitted).

In Daubert, the Court also clarified that parties should not be "overly pessimistic about the capabilities of the jury and of the adversary system generally." Daubert, 509 U.S. at 596. "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Id. "The role of the Court is not to determine 'the correctness of the expert's conclusions but the soundness of his methodology.'" Great W. Air, LLC v. Cirrus Design Corporation, No. 2:16-CV-02656-JAD-EJY, 2019 WL 6529046, *3 (D. Nev. 2019). "The judge is supposed to screen the jury from unreliable nonsense opinions… [t]he district court is not tasked with deciding whether the expert is right or wrong, just whether his testimony has substance such that it would be helpful to a jury." Id. at 4.

B. Dr. Bruce Rosenzweig's Testimony

1. Dr. Rosenzweig's Opinions About Non-Synthetic Mesh Procedures as Safer Alternatives Than Prolift and TVT

Ethicon argues that Dr. Rosenzweig's opinions about autologous slings and Burch colposuspension being safer alternatives than TVT for the surgical treatment of SUI, and his opinions that native tissue repairs like sacrocolpopexy and colporrhaphy are safer alternatives to Prolift for the surgical treatment of prolapse are irrelevant. It argues these opinions are irrelevant because they are about traditional *procedures* and not medical *devices* and thus these opinions cannot "inform the issue of whether an alternative design for a product exists." Plaintiffs argue that when treating POP, the *design* of the mesh used in Prolift makes it less effective than the traditional procedures that do not use mesh, and that Ethicon knew that synthetic, non-absorbable mesh was more likely to cause complications.

The Court is convinced by Defendant's argument that Dr. Rosenzweig's referral to alternative procedures do not entail changing the design of Prolift or TVT, but rather he essentially advocates eliminating them from SUI surgeries altogether "and utilizing a completely different surgical alternative." The Court finds that alternative procedures or surgeries do not

inform the jury how Ethicon could have made Prolift or TVT devices *themselves* safer to avoid the complications being claimed here. Further, this opinion could cause the jury to confuse the issues or waste time. See Rule 403.

Plaintiffs also argue that Dr. Rosenzweig's opinions are relevant to Ethicon's failure to warn and will help the jury to decide whether Ethicon included sufficient warnings with the TVT and Prolift mesh kits because of all the data comparing traditional surgical procedures and medical devices using mesh. Id. at 5. "Under Nevada law, to prove a failure to warn claim, a plaintiff must show (1) the product had a defect which rendered it unreasonably dangerous, (2) the defect existed at the time the product left the manufacturer, and (3) the defect caused the plaintiff's injury." Heinrich v. Ethicon, Inc., 455 F.Supp.3d 968, 972–73. "A product may be found unreasonably dangerous and defective if the manufacturer failed to provide an adequate warning." Id. A plaintiff must prove causation and can do so by "demonstrating that a different warning would have altered the way the plaintiff used the product or would have prompted plaintiff to take precautions to avoid the injury." Id.

However, "[t]he medical device manufacturer… is not in the best position to weigh the risks and benefits or using the device in a particular patient." Id. at 974. "Rather, 'the physician is in the best position to understand the patient's needs and assess the risks and benefits of a particular course of treatment.'" Id.

There is also no way for Ethicon, as merely the device manufacturer "to assess the suitability of its product for a particular patient in a particular situation" and there is no way for the manufacturer to "ensure that the patient receives the written warnings." Id. Because the traditional procedures Dr. Rosenzweig prefers are not medical devices being implanted in bodies, failing to warn patients about an entirely separate medical procedure is irrelevant to whether Ethicon failed to warn patients about possible defects in Prolift or TVT. Therefore, Dr. Rosenzweig may not testify specifically that the traditional procedures would have been a safer alternative than Prolift or TVT under an alternative design theory.

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2. Dr. Rosenzweig's Testimony Criticizing the Mechanical Cut of TVT

Dr. Rosenzweig proposes to testify that Ethicon knew that the mechanically cut mesh was not appropriate for use in its TVT device but failed to modify or change the mechanically cut mesh to a larger pore, lighter weight mesh that would not deform, fray, lose particles, rope, curl, degrade, cause excessive foreign body reactions, and cause excessive shrinkage or contraction. Further, he opines that laser cut mesh is inappropriate for use as a permanent implant because it is too stiff and rigid and causes pain and erosion and urinary dysfunction as a result.

The mesh in Mrs. Carter's TVT was mechanically cut. Ethicon argues that Dr. Rosenzweig should be precluded from criticizing the method used to cut Carter's mesh because neither Plaintiff's case-specific expert, Dr. Elliott, nor anyone else has opined that Mrs. Carter sustained any injury as a consequence of the way that the mesh was cut. Mrs. Carter argues in opposition that Dr. Rosenzweig's opinions are reliable.

The Court agrees with Ethicon that Carter's opposition goes solely to the reliability of Dr. Rosenzweig's testimony (which Ethicon does not attack) and does not address the relevance of Dr. Rosenzweig's testimony regarding the characteristics of mechanically cut mesh and laser cut mesh. Further, the Court agrees with Ethicon that Carter has failed to establish the relevance of such testimony because Dr. Elliott, as Carter's case-specific expert, "does not posit a causal relationship" between Carter's injuries and the method used to cut her mesh and Dr. Rosenzweig does not assert that laser cut mesh is a safer alternative to the mechanically cut mesh in Carter's device. Enborg v. Ethicon, Inc., 2022 WL 800879, *7 (E.D. Cal. March 16, 2022). Indeed, Dr. Rosenzweig calls for changes to the composition of the mesh, not a change in the method used to cut it. Finally, even if there were some relevance to this evidence, the Court finds that the probative value is substantially outweighed by the danger of unfair prejudice, confusion, and waste of time, in that it is likely to be misconstrued as causation or safer alternative testimony. See Rule 403.

Therefore, the Court grants Defendant's motion to limit Dr. Rosenzweig's testimony. He will be precluded from criticizing the method used to cut the mesh in Carter's TVT

device.

II. Conclusion

Accordingly, **IT IS HEREBY ORDERED** that Defendant's Motion to Limit Opinions of Daniel Rosenzweig, M.D. (#199) is **GRANTED**.

DATED this 30th day of September 2022.

Kent J. Dawson
United States District Judge